



# UNITED STATES PATENT AND TRADEMARK OFFICE

14

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,363	07/07/2003	Horst Dollinger	01/1359	7879

28501 7590 02/07/2007

MICHAEL P. MORRIS  
BOEHRINGER INGELHEIM CORPORATION  
900 RIDGEBURY ROAD  
P. O. BOX 368  
RIDGEFIELD, CT 06877-0368

EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/614,363

Applicant(s)

DOLLINGER ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,7-11,13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 and 12 is/are rejected.
- 7) ☒ Claim(s) 4-6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1-2, 11 and 13-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 20, 2006.

2. Applicant's election without traverse of invention group II in the reply filed on November 20, 2006 is acknowledged.

In the response, applicants particularly point out that claims 7-10 directed to compounds represented by formula IB. the examiner overlooks this group. It has been noted that formula IB are structurally distinct from formula IA as it substitute the ethylene moiety with an amide moiety. Therefore, the restrictions as set forth in the prior office action has been modified as follow: each of the groups set forth in the previous office action is subject to the following restriction:

A) drawn to invention of compounds of formula IA, or the method of making, or using the same;

B) drawn to invention of compounds of formula IB, or the method of making, or using the same;

C) drawn to invention of compound of formula I, wherein A is  $-C(=O)-CH_2-$  (for group I only).

1. Inventions A-C are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation. Particularly, the several inventions above are independent and distinct, each from the other, as they are directed to structurally distinct compounds, as the moiety, ethylene,

Art Unit: 1617

amide, and ketone have different chemical and physical properties, and they would render the compounds with different chemical, physical and biological properties. It is noted that a reference to one treatment would not be a reference to another treatment under 35 U.S.C. 103. Further, the claims read on a multitude of compounds, and a variety of disorders, which would require many field of searches that would be an undue burden on the Examiner. Therefore, restriction for examination purposes is proper.

It is well settled patent law that a Markush group must contain an immutable structural core responsible for the claimed activity. Applicant fails to provide an immutable central core structure for the proffered claims thereby presenting an improper Markush group for examination. Specifically, compounds with two phenyl groups as herein presented are known in the art (see, e.g., the references cited herein). Failure to link the claimed compounds with an immutable core structure results in claims reading on more than one invention, requiring restriction under 35 USC 121.

The above delineated inventions are independent and patentably distinct each from the other. The grouped inventions differ chemically, a reference which would anticipate the invention of one group would neither anticipate, nor make obvious the inventions in the other groups. The searches are not co-inclusive as indicated by the diverse chemical nature of the subject matter. One skilled in the art would readily practice the invention of one of the above groups without infringing and or practicing the invention of another group. The subject matter is unique and has acquired a separate status in the art and is fully capable of supporting separate patents. For the foregoing reasons restriction is proper for examination purposes.

Art Unit: 1617

Claims 7-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on November 20, 2006.

2. Applicant's election with traverse of compound disclosed in example 1D, read on claims 3-7 and 12 in the reply filed on November 20, 2006 is acknowledged. The traversal is on the ground(s) that compounds herein have been related structurally and functionally, and compounds of formula IB should be examined together. This is not found persuasive because the compounds are distinct each from the others for reasons set forth above.

3. Applicants' species election effectively elects group A.

4. The inventions has been examined is groups IIA. The elections of group A among the invnetions A-C is considered with traverse, in view of applicants' remarks about formula IB.

The requirement is still deemed proper and is therefore made FINAL.

The elected species is found allowable. Extended search also found that claims 4-6 are allowable.

#### ***Claim Objections***

5. Claims 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections 35 U.S.C. 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 3 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Protopopova et al. (US 6,951,961).

8. Protopopova et al. teaches substituted ethylene diamines and method of using the same as therapeutical agents. Compound 165 at column 57 and 58 is within the scope of formula IA herein.

***Claims Rejections 35 U.S.C. 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Neill (US 5,521,220).

11. O'Neill teaches compounds of phenyl substituted ethylene diamines as defined in columns 2. Particular compounds as defined in claim 1, and pharmaceutical composition comprising the same is claimed, wherein R<sub>4</sub>, a substituted aryl group, is linked to the amine moiety with a methylene group. See the claims.

Art Unit: 1617

12. O'Neill does not teach expressly a compounds wherein the R4 is linked to the amine moiety with a ethylene moiety.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to substitute the methlene moiety in O'Neill's compound with ethylene moiety, and thereby make the compounds as herein claimed.

A person of ordinary skill in the art would have been motivated to substitute the methlene moiety in O'Neill's compound with ethylene moiety, and thereby make the compounds as herein claimed because such structurally homologous compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are prima facie obvious, absent a showing of unexpected results. In re Hass, 60 USPQ 544 (CCPA 1944); In re Henze, 85 USPQ 261 (CCPA 1950).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1617

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shengjun Wang  
Primary Examiner  
Art Unit 1617

A handwritten signature in black ink, appearing to read "S. Wang".

SHENGJUN WANG  
PRIMARY EXAMINER